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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/522,248 | 01/25/2005 | Yasuo Hino | 4578-0113PUS1 | 8811 |

2292 7590 08/23/2006

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| EXAMINER |
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ROBERTS, LEZAH

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/522,248 | Applicant(s) HINO ET AL. | |
| | Examiner Lezah W. Roberts | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Action is in response to the Amendment filed June 1, 2006. All rejections have been withdrawn unless otherwise stated below.

Claims

Claim Rejections - 35 USC § 102 - Anticipation

1) Claims 1-3, 5-8, 10-12 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cornell (US 4,233,288). The rejection is withdrawn in regards to claims 1-3 and 5. The rejection is maintained in regards to claims 6-8, 10 and 14-15. Claims 11-12 are cancelled.

Applicant argues Cornell fails to disclose a wetting agent or any compositions wherein the amount and ratio of polyvalent alcohol and the amount and ratio of water-soluble polymer in the polymer composition are in the range of the present invention, i.e. 8-15 wt% and 4-30 wt% respectively. Applicant also argue the compositions require a higher content of polyvalent alcohol. The arguments are partially persuasive.

In regards to claims 1-3, and 5, the arguments are persuasive and the rejection has been withdrawn in reference to these claims. The instant claims 6-8, 10 and 14-15 have not been amended and recite a wt% range for the water-soluble polymer as 3 to

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25% weight percent and a range for the polyvalent alcohol as 1 to 60%, these ranges are still encompassed by the reference.

2) Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrow et al. (US 4,537,689). The rejection is withdrawn in regards to claims 1-5. The rejection is maintained in regards to claims 6-10 and 14-16.

Applicant argues the reference does not disclose Examples in which the ratio of water-soluble polymer to polyvalent alcohol falls into the range of the recited in the instant claims. Applicant also argues the requirements for lubricant compositions are not the same as the requirements for mouth wetting agents. The reference also does not disclose any suggestion for the ranges of the present invention. These arguments are partially persuasive.

In regards to claims 1-5, the arguments are persuasive and the rejection has been withdrawn in reference to these claims. The instant claims give a wt% range for the water-soluble polymer as 3 to 25% weight percent and a range for the polyvalent alcohol as 1 to 60%. The concentration of the thickeners in the compositions ranged from about 0.45% to about 2.4% by weight (see claim 3 of the reference). The referenced claim uses the term about 2.4% therefore this range encompasses 3% as recited in the instant claims. The term "about" permits some tolerance. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946) (as mentioned in the prior office action). In regards to the requirements for lubricant compositions not being the same as the requirements for mouth wetting agents, the requirements for the mouth wetting

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agents of the instant claims are the compositional make up. Since the compositions of the reference are substantially the same, comprising a water-soluble polymer and polyvalent alcohol in substantially the same concentrations, as the compositions of the instant claims, the requirements for the lubricant compositions and wetting agents of the instant claims are substantially the same. The reference anticipates the instant claims 6-10 and 14-16.

3) Claims 1, 3, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Turgeon (US 5,541,165). The rejection is withdrawn in regards to claims 1 and 3. The rejection is maintained in regards to claims 6 and 8.

Applicant's argues claim 2 has been incorporated into the independent claim and is not encompassed by the reference. Applicant also argues the reference does not teach using cellulose based polymers therefore the inventions are totally different from one another. This argument is persuasive in regards to claims 1 and 3. The argument is not persuasive in regards to claims 6 and 8.

Applicant recites the polymer of claims 6 and 8 as water-soluble polymer, which is encompassed by the Turgeon. Therefore the compositions of the reference are substantially the same, comprising a water-soluble polymer and polyvalent alcohol, are substantially the same as the compositions of the instant claims.

4) Claims 1, 3, 5-6, 8, 10, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al. (US 6,159,459). The rejection is withdrawn in regards

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to claims 1, 3 and 5. The rejection is maintained in regards to claims 6, 8, 10 and 15.

Claim 12 has been cancelled.

Applicant's argues claim 2 has been incorporated into the independent claim and is not encompassed by the reference. Applicant also argues the reference does not teach using cellulose based polymers therefore the inventions are totally different from one another.

Applicant recites the polymer of claims 6, 8, 10, 12 and 15 as water-soluble polymer, which is encompassed by the Hunter et al. The claims do not recite the water-soluble polymer is a cellulose based polymer. Therefore the compositions of the reference are substantially the same, comprising a water-soluble polymer and polyvalent alcohol, are substantially the same as the compositions of the instant claims.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6-10, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyd et al. (US 4,315,779).

Heyd et al. teach non-adhesive gel compositions for stabilizing dentures. The compositions contain a hydrophilic cellulose polymer, a demulcent and water, as recited in claims 1 and 6. The hydrophilic cellulose polymer may be selected from a group containing hydrophilic cellulose polymers or alginates. These groups include methylcellulose, ethylcellulose, methylethylcellulose, carboxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose and the like as well as the water-soluble salts of the cellulose polymers, such as for example, sodium carboxymethylcellulose, sodium carboxyethylcellulose and sodium carboxymethylhydroxyethylcellulose, as recited in claims 4, 7 and 9. The polymer may be incorporated into the compositions in an amount ranging from 1% to 10% by weight (col. 2, lines 22-68). The demulcents, or

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polyvalent alcohols as it is referred to in the instant claims, may be selected from a group containing glycerine, sorbitol and propylene glycol, which encompasses claims 3, 4, 8 and 9. They are included in the composition in a concentration ranging from 5% to 40% by weight. The preferred demulcent is glycerine (col. 3, lines 22-27). When the water-soluble polymer is 10%, the polyvalent alcohol may be 5% to 20%, encompassing the recited percentages and the weight ratios. The water comprises 50% to 95% by weight of the composition (col. 2, lines 7-8). Other components may be added to the compositions such as sodium chloride. Sodium chloride can be added to the compositions to adjust the tonicity of the composition (col. 28-31). The table in column 4 encompasses claims 10 and 14-16. The reference differs from the instant claims insofar as it does not include specific examples wherein the water-soluble polymer is 100 parts by weight and the polyvalent alcohol is 50 to 200 parts by weight.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the amounts of water-soluble polymer and polyvalent alcohol used in the compositions motivated by the desire to obtain suitable properties for the compositions, as supported by cited case law.

Claims 1, 4-10 and 14-16 are rejected.

Claims 2-3 and 11-13 are cancelled.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

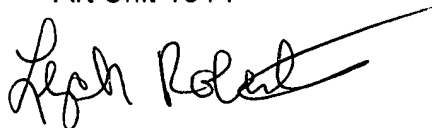
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

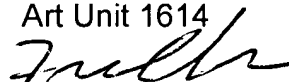
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Lezah Roberts', with a long horizontal stroke extending to the right.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Frederick Krass', with a stylized, cursive script.